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Document Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852

RE: Document number 97N-484S

Dear Sirs:

I am recommending that you do not increase the regulation of bone tissue. It already is regulated for safety and I do not know of any adverse events as a result of the current management system. Consequently, I object to putting on another layer of FDA regulations.

Sincerely yours,

Ray V. Grewe, M.D.

Neurosurgeon

RVG:gts/bp

97N-4845

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